DOCKET NO.: CEPF-0015 PATENT

Application No.: Not Yet Assigned

Office Action Dated: Preliminary Amendment

This listing of claims will replace all prior versions, and listings, of claims in the application.

## **Listing of Claims:**

1. (Original) Process for preparing modafinil having a defined granulometry which comprises the steps of:

- a) preparing a solution of DMSAM in a solvent;
- b) contacting the solution obtained with NH<sub>3</sub> at a predetermined temperature and under a predetermined stirring; and
- c) isolating the modafinil formed, wherein said temperature and said stirring are predetermined in order to obtain said defined granulometry.
  - 2. (Original) Process according to claim 1, wherein the solvent is a protic polar solvent.
  - 3. (Original) Process according to claim 2, wherein the solvent is an alcohol.
  - 4. (Original) Process according to claim 3, wherein the solvent is methanol.
- 5. (Original) Process according to claim 4, wherein the solution of DMSAM has a concentration of DMSAM of between 1 and 1.25 mol L<sup>-1</sup>.
- 6. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the temperature in step b) is held between 15 and 65°C.
- 7. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the predetermined stirring speed in step b) is chosen such that the modafinil isolated in step c) has a granulometric median of between 2 and 60  $\mu$ m, preferably between 15 and 45  $\mu$ m.
- 8. (Currently amended) Process according to any one of the preceding claims claim 1, wherein in step b), the solution of DMSAM is contacted with 3 to 6 molar equivalent of NH<sub>3</sub>.

**DOCKET NO.:** CEPF-0015

Application No.: Not Yet Assigned

Office Action Dated: Preliminary Amendment

9. (Original) Process according to claim 8, wherein, in step b), the solution of DMSAM is contacted with 3.2 and 5 molar equivalent of NH<sub>3</sub>.

PATENT

- 10. (Currently amended) Process according to any one of the preceding claims claim 1, wherein, in step b), the NH<sub>3</sub> is introduced into the solution over a sufficient time to obtain a complete dissolution of NH<sub>3</sub>.
- 11. (Original) Process according to claim 10, wherein, in step b), the NH<sub>3</sub> is introduced into the solution over a time of between 2 h and 6 h.
- 12. (Original) Process according to Claim 11, wherein, in step b), the NH<sub>3</sub> is introduced into the solution over a time of between 3 h and 4.5 h.
- 13. (Currently amended) Process according to any one of the preceding claims claim 1, wherein, in step b), the solution is contacted after the introduction of the NH<sub>3</sub> for a contact time sufficient to allow the polymorphic transformation of form III to form I.
- 14. (Original) Process according to claim 13, wherein the contact time is between 8 and 12 h.
  - 15. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the solution obtained after step b) is further maintained at a temperature lower than the predetermined temperature of step b) for a time sufficient to obtain complete crystallization of modafinil.
  - 16. (Original) Process according to claim 15, wherein the solution is further maintained at a temperature lower than the temperature of step b) for a time of from 1 h to 4 h.

DOCKET NO.: CEPF-0015

Application No.: Not Yet Assigned

Office Action Dated: Preliminary Amendment

17. (Currently amended) Process according to elaims claim 15 and 16, wherein the temperature is between -20°C and 0°C.

PATENT

- 18. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the modafinil is isolated in step c) by filtration.
- 19. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the solvent in step a) comprises water.
- 20. (Original) Process according to claim 19, wherein the solvent contains from 5% to 20% by volume of water.
- 21. (Currently amended) Process according to any of claims 19 or 20 claim 19, wherein the NH<sub>3</sub> is introduced into the solution in step b) over a time of between 4 h and 5 h.
- 22. (Currently amended) Process according to any of claims 19 to 21 claim 19, wherein, in step b), the solution of DMSAM is contacted with 5 to 5.5 molar equivalent of NH<sub>3</sub>.
  - 23. (Currently amended) Process according to any one of the preceding claims claim 1, which does not include a recrystallization step after step c).
- 24. (Currently amended) Process according to any one of the preceding claims claim 1, which does not include a grinding step after step c).
  - 25. (Currently amended) Process according to any one of the preceding claims claim 1, wherein the predetermined temperature and stirring speed are chosen such that particles of modafinil form I of which at least:
    - 50% have a diameter of less than 45 μm, and
    - 80% have a diameter of less than 110 μm, and
    - 95% have a diameter of less than 220 μm,

Page 5 of 7

**DOCKET NO.:** CEPF-0015

Application No.: Not Yet Assigned

Office Action Dated: Preliminary Amendment

are isolated in step c).

26. (Currently amended) Process according to any of claims 1 to 12 and 15 to 24 claim 1, wherein the modafinil isolated in step c) is modafinil form III.

**PATENT** 

- 27. (Currently amended) Process according to any of claims 1 to 24 claim 1, wherein the modafinil isolated in step c) is modafinil form I.
- 28. (Currently amended) Process according to any of claims 1 to 24 claim 1, wherein modafinil with a granulometric median of between 1 μm and 1 mm is isolated in step c).
- 29. (Original) Process according to claim 1, wherein the levorotary enantiomer of DMSAM is employed in step a).
- 30. (Original) Process according to claim 1, wherein the dextrorotary enantiomer of DMSAM is employed in step a).
- 31. (Currently amended) A modafinil obtainable by the process according to any one of the preceding claims claim 1.